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| 10/646,801 | 08/25/2003 | Douglas A. Schein | 115621 | 1325 |
| 25944 7590 10/27/2009 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850 | | | | |
| EXAMINER | | | | |
| YABUT, DIANE D | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,801

Applicant(s)

SCHEIN ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38, 40, 43, 44 and 65-103 is/are pending in the application.
- 4a) Of the above claim(s) 24-35, 43 and 65-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 36-38, 40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 06/12/2009.

The examiner acknowledges the amendments made to the claims.

Claims 1-38, 40, 43-44, and 65-103 are pending in this application. Claims 24-35, 43, 65-103 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-2 are 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by **Barbut** (U.S. Patent No. **6,355,010**).

In Figures 4-6 and 8-9 Barbut discloses a first portion and a second portion **214** that form a chamber when brought together, and a first fitting **222** disposed on one of the first and the second portions, the first fitting being in fluid communication with the chamber, the second portion having a hole **212** in fluid communication with the chamber and adapted to receive a section of tissue of an organ **14, 18**, at least one sealing surface **219** being adapted to secure the section of tissue when the first and second portions are brought together, and the first fitting and the hole being adapted to allow fluid flow from an external fluid flow system into the section of tissue. The fluid flow through the first fitting is substantially perpendicular to fluid flow through the hole (Figures 4-5). A pre-positioning structure is formed on the first portion (surrounding hinge **218**) and a complementary pre-positioning structure is formed on the second portion, which are arranged to engage each other (via the hinge **218**) while permitting relative pivoting or linear movement (as in a linear or constant rate of movement) of the first and second portions such that a first sealing surface on the first portion is substantially parallel to a second sealing surface on the second portion to secure tissue (Figures 5-6). The portion surrounding hinge **218** may also be considered to be a flange extending from an outer surface of the second portion (Figure 5).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbut** (U.S. Patent No. **6,355,010**).

Barbut discloses the claimed device except for at least one of the first and second portions that forms part of the chamber is one of a transparent material and a translucent material. However, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Barbut by forming either of the first and second portions **214** with a transparent or translucent material in order to facilitate visualization of the tissue being sealed, to ensure proper fluid flow, and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

5. Claims 4-8, 36-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbut** (U.S. Patent No. **6,355,010**) in view of **Robinson** (U.S. Patent No. **6,726,651**).

Barbut discloses the claimed device, but does not expressly disclose having the chamber being designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole, or having a second fitting formed on one of the first and second portions and being in fluid communication with the chamber that is formed when the first and second portions are brought together, the fluid flow being substantially perpendicular through the second fitting to the fluid flow through the hole, and the second fitting comprising at least one of a vent and a valve, the second fitting being connectable to a first fitting.

Robinson teaches a perfusion cannula “chamber” **1220** designed to collect gas separate from a fluid flow through a first fitting, the chamber and the hole, or having a second fitting formed on one of the first and second portions and being in fluid communication with the chamber that is formed when the first and second portions are brought together, the fluid flow being substantially perpendicular through the second fitting to the fluid flow through the hole, and the second fitting comprising at least one of a vent and a valve **1240**, the second fitting being connectable to a first fitting (Figure 23). There are multiple fittings (near reference numerals **1230**, **1274**, **1218**). Any of the fittings are adapted to connect to a first fitting of a second cannula. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second

fitting, as taught by Robinson, to Barbut in order to introduce various materials into the cannula while creating a fluid-tight seal.

6. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbut** (U.S. Patent No. **6,355,010**) in view of **Golyakhovsky** (U.S. Patent No. **4,800,879**).

Barbut discloses the claimed device, including an engagement member and a complementary engagement member (surrounding hinge **218**) that engage together while permitting relative movement of the first and second portions such that the first portion is substantially parallel to a second sealing surface on the second portions. However, Barbut lacks at least one fixing member on one of the first and second portions, and at least one compression strap arranged to wrap around at least part of the first portion and at least part of the second portion and to engage the fixing member so that the first and second portions are brought together, and further a sealing ring disposed between the first and second portions, the compression strap extending from the sealing ring, wherein the engagement member is arranged to engage the complementary member while the compression strap is wrapped around at least part of the first portion and at least part of the second portion and engages the fixing member so that the first and second portions are brought together.

Golyakhovsky discloses at least one fixing member **14b** and at least one compression strap **14a** arranged to wrap around a first portion and a second portion and to engage the fixing member so that the first and second portions are brought together,

the compression strap extending from a sealing ring (the top part of first portion 1 that contacts tissue) and a complementary engagement member (near 3) at a free or opposite end of the compression which is wrapped around at least a part of the first portion and the second portion and engages the fixing member so that the first and second portions are brought together (Figures 1-3). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Barbut by providing a fixing member and compression strap on an outside surface of the first and second portions , as taught by Golyakhovsky, in order to facilitate sealing of the tissue by latching the first and second portions together while minimizing trauma to the tissue (see abstract).

7. Claims 18-23 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbut** (U.S. Patent No. **6,355,010**) in view of **Valley** (U.S. Patent No. **5,814,016**).

Barbut discloses the claimed device, including ridges **219** (Figure 6), but does not expressly disclose a sealing ring disposed between the top and bottom portions made of an elastomeric material, the ring having a complementary shape to the sealing surfaces.

Valley teaches a sealing ring **883** disposed between the top and bottom portions made of an elastomeric material, the ring having a complementary shape to the sealing surfaces (Figure 33, col. 45, lines 50-56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a sealing ring, as taught by Valley, to Barbut since it was well known in the art to provide an elastomeric sealing ring or gasket member in between two engaging members to avoid leaks.

Response to Arguments

8. Applicant's arguments with respect to claims 1-23, 36-38, 40, and 44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DIANE YABUT** whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734